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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/320,100 05/26/99 ANSALDI

D P1363R1

EXAMINER

HM12/1208

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HUNT, J	
ART UNIT	PAPER NUMBER

1642

4

DATE MAILED:

12/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/320,100

Applicant(s)

Ansaldi et al.

Examiner

Jennifer Hunt

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 are unclear in the recitation of "a method which is disclosed". The recitation of a claim of "a method is disclosed" is improper.

Claims 2-3 are unclear in the recitation of a monomer polypeptide. The claims and specification disclose two specific examples of the contemplated method, purification of antibodies and BSA. It is known in the art that antibodies are dimers unless they have been cleaved to form monomeric antibody fragments. The specification does not define what is meant by the term "Ab monomer". As claimed, it is not clear if properly folded antibody is to be separated from aggregates or if standard antibody dimers of 2 heavy and 2 light chains are to be separated into single chain antibodies. Applicant is requested to clarify the claim language. One example which would clarify the claimed method is to recite a method of purifying properly folded peptides from improper protein dimers or aggregates.

Art Unit: 1642

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-7, and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al, Journal of Chromatography, A 743, 1996.

To the extent that the claimed invention reads on purification of antibodies, Yang et al teaches a method of purifying antibodies from a mixture containing dimers, multimers, or both, wherein the method comprises applying the mixture to a cation exchange chromatography resin with numerous pH's in the 6-7 range or a anion exchange resin with numerous pH's in the 6-9 range.(pages 173-177) The method of Yang utilizes a linear gradient and the elution salt sodium chloride at a gradient slope of 0 to 500mM, which includes gradients of 0-50 and 50-200nM (page 178-179).

5. Claims 1, 2, 5, and 8-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Hahn et al, Chromatography 795, 1998 pp277-287.

Hahn et al. teaches a method of separating polypeptide monomers from a mixture wherein the method comprises applying the mixture to a cation exchange chromatography resin

Art Unit: 1642

with pH's from 4.7-5.4. The method of Hahn utilizes a stepwise gradient of 0-1000mM and the elution salt sodium chloride.(pages 280-282)

6. Claims 1, 5, 7, 9, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,765,903, D'Andrea et al.

'903 teaches a method of separating a polypeptide monomer from a mixture containing dimers by cation exchange at a pH of 5.2 and eluting the mixture on any sodium gradient between 200nM and 1M.(column 6, line 46-column 7, line23)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2 and 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al., in view of US Patent 4,764,279, Tayot et al.

Claims 1,2, and 5-13 are rejected over Yang et al and Hahn et al as set forth supra. Yang et al. fails to teach the separation of the specific polypeptide Bovine Serum Albumin (BSA) from a mixture comprising dimers, however Yang et al. does set forth the desirability of separating BSA from IgG and that the method of Yang et al. is useful for this separation. Yang et al.

Art Unit: 1642

Further teaches the addition of BSA to antibody preparations, which addition is standard, well known art technology for stabilization.

'279 teaches an anion exchange method of separating albumin from a mixture comprising dimers with a pH between 4.8 and 6.8 and obtaining the albumin by elution. '279 also teaches that the separation is desirable to produce industrial scale albumin.

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify BSA using the method of Yang et al. with a reasonable expectation of success as demonstrated by Yang et al., and one would have been motivated to do so because BSA is useful as an industrial protein as taught by Yang et al. and the separation method is taught to be industrially applicable by 4,764,279.

9. Claims 1-3 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al and Hahn et al., in view of Oncogene Science catalog 1992, pages 18 and 35.

Claims 1,2, and 5-13 are rejected over Yang et al and Hahn et al as set forth supra. Yang et al. and Hahn et al. fail to teach the specific antibodies: anti-IgE, anti-IgG, anti-Her-2, anti-CD11a, anti CD 18, anti-CD20, or anti-VE.

Oncogene Science catalog teaches that numerous oncogenes, growth factors, and CD antibodies, including anti-HER2 and anti-CD18 are known and that it is desirable to produce and purify them for industrial use.(pages 18 and 34-35)

Therefor it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the cation or anion exchange methods of Yang et al and Hahn

Art Unit: 1642

et al, to purify any desirable peptide, including specific antibodies, such as anti-HER2 or anti-CD18 with a reasonable expectation of success given the general art-known usefulness of the methods for purification and standard technical optimizations and one would have been motivated to do so given the art-known desirability of such antibodies, as exemplified by Oncogene Science.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paulahutzell@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly

Art Unit: 1642

signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt


YVONNE EYLER, PH.D
PRIMARY EXAMINER

November 22, 1999